REMARKS/ARGUMENTS

Claims 1-63 and 65 are pending in this application. Claims 1 and 45 have been amended to more clearly define applicants' invention. The claim amendments are all entirely supported by the application as originally filed and thus they raise no issue of new matter. The Examiner is respectfully requested to enter and consider the claim amendments and arguments presented herein since they are believed to place this application in condition for allowance or, at a minimum, to materially reduce the issues for an appeal. Upon such entry, claims 1-63 and 65, as amended, will be pending in this application

The rejections set forth in the present Office Action are essentially identical to those raised by the Examiner in his previous (i.e., first) Office Action concerning this application. In the Amendment submitted by the applicants on July 10, 2006 in response to such previous Action, the grounds for rejection were extensively discussed in an effort to bring to the Examiner's attention those features which, in applicants' view, render the presently claimed invention both novel and non-obvious over the cited prior art. Those remarks are specifically incorporated herein by reference and, thus, it is believed to be unnecessary to repeat them in this response.

Nevertheless, despite the amendments/arguments contained in the July 10th response, the Examiner continues to adhere to his previous grounds for rejection and his reasons for so doing are presented in detail in this Office Action. The remarks which follow, therefore, are particularly responsive to, but are not limited, to the Examiner's additional arguments presented in the final Office Action for this case, dated November 13, 2006.

Discussion of Claim Rejections

In ¶4 of the Office Action, (method) claims 45-48, 50, 51, 54, 56 and 63 are rejected under 35 USC 102(b) as allegedly anticipated by Stern et al. USP 5,912,014. This rejection is respectfully traversed.

In response to the rejection based on Stern et al. '014, applicants have amended (independent) claim 45 to further distinguish it from the cited reference. That is, the claim as amended now recites, in step (A), that the peptide agent is amidated *at a location that is not*

normally amidated. This feature is not taught or described in the '014 patent and, thus, claim 45 as amended is believed to exhibit Novelty over the cited reference. The Examiner is, therefore, requested to reconsider and withdraw the rejection of claim 45 for anticipation over Stern et al. '014. The remaining rejected claims, i.e., nos. 46-48, 50, 51, 54, 56 and 63 each depend, directly or indirectly from claim 45 and thus they contain all of the limitations found in the subject independent claim. They are, therefore, believed to distinguish over the cited '014 reference for the same reasons as claim 45 and thus the rejection of these claims should be withdrawn as well.

In ¶5 of the Office Action, (method) claims 45-47, 50, 51, 54, 56, 61 and 63 are rejected under 35 USC 102(b) as allegedly anticipated by Stern et al. USP 6,086,918. This rejection is also respectfully traversed.

As discussed above with regard to the §102(b) rejection based on Stern et al. '014, applicants submit that the amendment herein of claim 45 to recite that the peptide agent is amidated, "at a location that is not naturally amidated" also renders the subject claim and those rejected claims depending from that claim entirely Novel over the disclosure contained in the '918 reference. That is, the Stern et al. '918 reference neither teaches nor even suggests to one having ordinary skill in this art to take the step of amidating an orally delivered peptide agent, for purposes of enhancing its bioavailability, at a location that is not normally amidated. As such, the Examiner is respectfully requested to reconsider and withdraw his anticipation rejection of claim 45 over Stern et al. '918. Furthermore, the remaining rejected claims all depend, directly or indirectly, from claim 45 and thus contain all of the recitations found within the subject independent claim. Thus, those dependent claims are also believed to distinguish the invention over the cited reference and the rejection of those claims should, therefore, be withdrawn as well.

In ¶6 of the Office Action, claims 1-8, 12-47, 49-51, 54-60, 62, 63 and 65 are rejected for 'obviousness' under 35 U.S.C. §103 over Stern et al. '918 and further in view of Habener (USP 5,120,712), Balschmidt et al. (USP 5,157,021), Barbier et al. (USP 6,110,892), European Patent Application 878,201 or Neiss et al. (USP 4,804,742). This rejection, also, is respectfully traversed.

Applicants submit that there are presently three independent claims pending in this application, i.e., no. 1 which broadly recites an oral pharmaceutical composition; no. 65 which is directed to an oral pharmaceutical composition adapted for delivery of a specific peptide, i.e.,

human parathyroid hormone analog PTH[1-34]-OH and no. 45 which recites a method for enhancing the bioavailability of an orally delivered physiologically active peptide agent. For purposes of clarity, therefore, the remarks provided below are directed toward explaining how each of these independent claims distinguish over the various combinations of references set forth in the Office Action. As indicated above, moreover, the claims which depend from the subject independent claims are deemed to be distinguishable over the references for at least the same reasons as the independent claims since they include all of the limitations contained in the respective independent claim from which they depend.

Turning first to claim 1, applicants have amended the subject claim such that it now recites, *inter alia*, that the claimed pharmaceutical composition: (a) is an oral composition; (b) is adapted to provide enhanced bioavailabiliy of an orally delivered physiologically active peptide agent; and (c) comprises an active peptide amidated at location that is not naturally amidated. With regard to the cited references, Stern et al. '918 does not disclose to provide (as is now specifically recited in the amended claim) enhanced bioavailability to any orally delivered active peptide agents encompassed therein by amidating them at a location that is not naturally amidated. The Examiner, therefore, has combined the subject reference with one or more 'secondary' references which, it is alleged by the Office Action, teach various amidated peptide agents encompassed by applicants' claims.

Applicants are not, however, claiming that they have 'invented' amidated peptide agents or that the claimed invention is simply a pharmaceutical composition including an amidated active peptide agent. Rather, what is now recited in applicants' claim 1 is an oral composition adapted to provide enhanced bioavailability (of an orally delivered active peptide agent), wherein the adaptation constitutes amidating the active peptide agent at a location that is not naturally amidated such that the resultant composition is provided with enhanced bioavailability. Thus, to begin with, the only relevant teaching to be found in any of the secondary references must concern not simply amidated peptides, but rather, peptides which are amidated at a location which is not naturally amidated. Further, the Examiner has not pointed to any teaching contained in any of the subject references which would suggest to one having ordinary skill in this art that the inclusion of an active peptide amidated at such a location wherein it is not naturally amidated,

would serve to adapt a pharmaceutical composition such that it would provide an enhanced bioavailability of the peptide agent, i.e., in contrast to a composition which lacks the adaptation.

Still further, applicants respectfully reiterate the argument made in their earlier response that a number of the secondary references are not directed to "oral pharmaceutical compositions" as that term is used in claim 1. For example, Habener teaches to administer the compositions described therein, "intravenously, intramuscularly or subcutaneously". Additionally, Balschmidt teaches to use injectable formulations. Barbier also teaches to administer via injection. European Application 878,201 teaches to inject as well. The Examiner counters this argument by noting that at least some of the subject references teach that the peptide compositions may be prepared in liquid form, thus making it possible to deliver the peptide(s) orally. This position is, however, respectfully traversed as applicants submit that just because a formulation is prepared in liquid form and thus could be readily swallowed does not mean that it is ever intended by its maker to be administered orally.

It is, therefore, respectfully submitted that claim 1 is distinguishable over the references combined by the Examiner in ¶6 of the Office Action, as are the rejected claims which depend from that claim. The Examiner is, therefore, respectfully requested to reconsider and withdraw the rejection under §103 of claim 1 and its dependent claims over the references in ¶6.

Turning to the rejection of claim 65, applicants submit that the subject claim is directed to an oral pharmaceutical composition adapted to orally deliver a particular active peptide material, i.e, PTH1-34 in the free acid form (PTH1-34-OH). Stern et al. '918 does mention, "parathyroid hormone" at col. 6, line 5, but there is, however no teaching or even a suggestion to use a truncated fragment of such a parathyroid hormone and, even more particularly, the specific truncated fragment recited in applicants' claim 65, i.e., PTH1-34-OH. For at least these reasons, therefore, claim 65 is believed to be distinguishable over Stern et al. '918.

Applicants recognize, of course, that the rejection of claim 65 is based on a combination of references and not just on Stern et al. '918. However, notwithstanding the disclosure contained in any of the secondary references which may teach or suggest the particular truncated fragment recited in the claim (1-34 in the free acid form) - see, e.g., the Examiner's description relating to Barbier and European Patent Application '201, neither of those references (nor any other(s) of the cited secondary references) could be said to suggest the use of such PTH1-34-OH

in the oral delivery 'system' described in Stern et al. '918. That is to say that just because a secondary reference teaches a truncated (1-34) parathyroid hormone fragment (either amidated or in the free acid form), that should not be taken as a suggestion to incorporate that fragment into the oral delivery pharmaceutical composition described in Stern et al. '918.

For at least the reasons above, therefore, applicants submit that claim 65 is distinguishable over the combination set forth in ¶6 of the Office Action and the Examiner is, therefore, respectfully requested to reconsider and withdraw the subject rejection of claim 65 under 35 USC 103 over the references discussed above.

The remaining independent claim is method claim 45 which, as noted above, has been amended in this response to include the step of amidating the active peptide agent at a location that is not naturally amidated. The rejection of claim 45, as well as the rejection of those claims which depend from the subject claim, are respectfully traversed.

As previously discussed herein, Stern et al. '918 would not teach or suggest to one having ordinary skill in this art the use of a physiologically active peptide that is amidated at a location where it is not naturally amidated. Thus, the claimed method is distinguishable over that reference. Turning to the secondary references combined with Stern et al. '918, the issue is NOT whether or not any of those references disclose such a "physiologically active peptide that is amidated at a location where it is not naturally amidated." Rather, the proper issue for determination is whether any of those references would suggest to replace the peptides described in the '918 patent with such a 'peptide amidated at a location where it is not normally amidated, for the purpose recited in claim 45, i.e., that of enhancing the bioavailability of an orally delivered physiologically active peptide agent - taking into account that the claim is directed to a method and not a composition.. Applicants' position, of course, is that NONE of the subject references suggests such a substitution, whether they are taken singly or in any combination.

As such, applicants respectfully contend that claim 45 and those claims which depend therefrom are completely distinguishable over the combination of references cited by the Examiner in ¶6 of the Office Action. The Examiner is, therefore, requested to reconsider and withdraw the rejection of the subject claims.

In ¶7 of the Office Action, (method) claims 45-48, 50-54-56, 61 and 63 are rejected as allegedly anticipated over International Publication No. WO 02/043767 of Unigene Laboratories,

Inc. (the Assignee of the present application) directed to, "Improved Oral Delivery of Peptides Using Enzyme-Cleavable Membrane Translocators". This rejection is respectfully traversed.

In applicants' previous response, it was argued that The Unigene publication does not display any recognition to amidate a physiologically active peptide for the purpose of increasing or otherwise enhancing its bioavailability. In contrast, it teaches to increase bioavailability by linking the peptide agent to a membrane translocator (MT) that is capable of being at least partially cleaved by a plasma protease, and by selectively releasing the peptide so linked with a pH-reducing agent and/or a protease inhibitor into a patient's intestine following passage through the mouth and stomach while protected by an enteric coating. Despite the fact that the Unigene reference disclosed the use of peptides that are amidated, there is no recognition by the reference, i.e., no teaching of a cause and effect relationship between the amidation of a peptide and increasing its bioavailability.

In the present Office Action, however, the Examiner has responded by arguing that, in the case of a peptide which is already amidated, there must have been a previous step wherein the peptide was amidated to form such an amidated peptide. Thus, in the view of the Examiner it would be obvious to practice the steps of (1) amidating a peptide and (2) orally administering such amidated peptide.

In consideration of the Examiner's reply in the present Office Action, the applicants have amended claim 45 such that step (A) involves amidating the peptide "at a location that is not naturally amidated". This step is not taught, nor even suggested, anywhere within the cited publication. Even agreeing, for the sake of argument, that amidated peptides are known and to form such peptide(s) involves amidating an existing peptide, this knowledge would in no way teach or even suggest to one having ordinary skill in this art that one could achieve the aim recited in claim 45, i.e., that of enhancing the bioavailability of an orally delivered physiologically active peptide agent, by "amidating such peptide agent at a location that is not naturally amidated."

Further evidence that the disclosure of the International Publication does not render obvious the presently claimed invention is provided by the fact that, as would be well understood by one of ordinary skill in this art, the membrane translocator is taught for addition in the subject reference to the N terminus of a peptide, whereas in the case of the present invention as described

in the teachings contained in applicants' specification the amidation takes place at the other end, i.e., the C terminus, of the peptide. Applicants thus submit that such a teaching as contained in WO 02/043767 to modify the N terminus of, e.g., a peptide would not tend to teach or suggest to modify the C terminus, i.e., to amidate the peptide at a location where it is not naturally amidated.

The Examiner is, therefore, respectfully requested to reconsider and withdraw the anticipation rejection of claim 45 based upon the Unigene publication. Furthermore, the rejected claims depending from claim 45 are also believed to be distinguishable over the subject reference for the same reasons as claim 45 as these claims all include all of the recitations contained in claim 45 due to their dependency (whether direct or indirect) upon that claim.

Still further, in ¶8 of the Office Action, claims 1-47, 49-60, 62, 63 and 65 are rejected under 35 U.S.C. 103 as allegedly obvious over the Unigene publication (WO 02/43767) and further in view of Habener (USP 5,120,712), Balschmidt et al. (USP 5,157,021), Barbier et al. (USP 6,110,892), European Patent Application 878,201 or Neiss et al. (USP 4,804,742). This ground of rejection is respectfully traversed. In like manner to the rejection of claims 1-8, 12-47, 49-51, 54-60, 62, 63 and 65 as discussed above, the Examiner in this case cites a 'primary' reference, i.e., WO 02/43767 which according to him lacks (at least) the necessary disclosure concerning amidated peptides, and then combines the primary reference with one or more 'secondary' references cited due to their disclosure regarding such amidated peptides. Thus, the rejection is traversed, as explained below, for essentially the same reasons as the rejection as claims 1-8, 12-47, etc..

Focusing on the independent claims included in the subject rejection, claim 1 is directed to an oral pharmaceutical composition which is adapted to provide enhanced bioavailability of an orally delivered physiologically active peptide agent by virtue of the peptide being amidated at a location where it is not naturally amidated. According to the Office Action, the primary reference (WO 02/43767) discloses the invention except for the amidated peptide feature, and thus the primary reference is combined with one or more secondary references which disclose, *inter alia*, such amidated peptides. Applicants respectfully submit, however, that even in combination the references do not teach or suggest the claimed invention since there is nothing to be found in either the primary reference or any of the secondary references which would suggest

a composition capable of providing enhanced bioavailability of an orally delivered peptide by virtue of providing, in said composition, a peptide which has been amidated at a location where it is not naturally amidated as is recited in claim 1. Simply noting, as the Examiner has done in the Office Action, that the primary reference discloses oral peptide compositions while the secondary reference(s) describe amidated oral peptides (some of which being amidated at locations which are not naturally amidated - see, e.g., Neiss et al. USP 4,804,742) is not enough. The combination of references must also demonstrate a recognition by their authors that the composition would have enhanced bioavailablility of the oral peptide agent when one amidates such peptide agent at a location that is not naturally amidated. For the reasons above, therefore, claim 1 and those claims which depend therefrom are believed to distinguish the invention over the combination of references cited in ¶8 of the Office Action.

Turning to the rejection of claim 65, applicants submit that the subject claim is directed to an oral pharmaceutical composition adapted to orally deliver a particular active peptide material, i.e, PTH1-34 in the free acid form (PTH1-34-OH). WO 02/43767 does mention, "parathyroid hormone" at pps. 5 and 17, but there is, however no teaching or even a suggestion to use a truncated fragment of such a parathyroid hormone and, even more particularly, the specific truncated fragment recited in applicants' claim 65, i.e., PTH1-34-OH. For at least these references, therefore, claim 65 is believed to be distinguishable over WO 02/43767.

The rejection of the subject claim is, of course, based on a combination of references and not just on WO 02/43767. However, notwithstanding the disclosure contained in any of the secondary references which may teach or suggest the particular truncated fragment recited in the claim (1-34 in the free acid form) - see, e.g., the Examiner's description relating to Barbier and European Patent Application '201, neither of those references (nor any other(s) of the cited secondary references) could be said to suggest the use of such PTH1-34-OH in the oral delivery 'system' described in WO 02/43767. That is to say that just because a secondary reference teaches a truncated (1-34) parathyroid hormone fragment (either amidated or in the free acid form), that should not be taken as a suggestion to incorporate that fragment into the oral delivery pharmaceutical composition described in WO 02/43767.

For at least the reasons above, therefore, applicants submit that claim 65 is distinguishable over the combination set forth in ¶8 of the Office Action and the Examiner is,

therefore, respectfully requested to reconsider and withdraw the rejection of claim 65 under §103 over the references discussed above.

The remaining independent claim is method claim 45 which, as noted herein, has been amended in this response to include the step of amidating the active peptide agent at a location that is not naturally amidated. The rejection of claim 45, as well as the rejection of those claims which depend therefrom, are respectfully traversed.

As previously discussed herein, WO 02/43767 would not teach or suggest to one having ordinary skill in this art the use of a physiologically active peptide that is amidated at a location where it is not naturally amidated. Thus, the claimed method is distinguishable over the subject reference. Turning to the secondary references combined with WO 02/43767, the issue is NOT whether or not any of the subject references disclose such a "physiologically active peptide that is amidated at a location where it is not naturally amidated." Rather, as noted above in the discussion of the rejections found in ¶6 of the Office Action, the proper issue for determination is whether any of those references would suggest to replace the peptides described in the WO 02/43767 reference with such a 'peptide amidated at a location where it is not normally amidated, for the purpose recited in claim 45, i.e., that of enhancing the bioavailability of an orally delivered physiologically active peptide agent - taking into account that the claim is directed to a method and not a composition.. Applicants' position, of course, is that NONE of the subject references suggests such a substitution, whether they are taken singly or in any combination.

As such, applicants respectfully contend that claim 45 and those claims which depend therefrom are completely distinguishable over the combination of references cited by the Examiner in ¶8 of the Office Action. The Examiner is, therefore, requested to reconsider and withdraw the rejection of the subject claims.

Still further, in ¶9 of the Office Action (composition) claims 1, 6 and 39 are rejected as anticipated under 35 USC 102(b) over USP 5,157,021 to Balschmidt et al. This rejection is respectfully traversed.

In their previous response, applicants argued that (the previous version of) claim 1 was distinguishable over the cited reference in that claim 1 was directed to an oral pharmaceutical composition whereas Balschmidt et al. taught an injectable formulation. The Examiner

countered applicants' argument with the statement that a 'statement of intended use', i.e., "for oral delivery" in claim 1 does not provide a patentable distinction. In response, applicants have amended claim 1 to more clearly recite their invention such that, as now constituted, it recites (1) an oral pharmaceutical composition - not a pharmaceutical composition 'for oral delivery'; (2) that provides enhanced bioavailability of the orally delivered physiologically active peptide agent; (3) wherein such enhanced bioavailability is provided due to amidating the peptide active agent at a location where it is not naturally amidated. There is no recognition evidenced in Balschmidt et al. that amidating the peptide at the indicated location (i.e., where it is not naturally amidated) will have any effect on the bioavailability of the subject peptide.

Additionally, per the discussion above, the presently claimed formulation is recited in claim 1 as being an "oral pharmaceutical composition", not a composition adapted "for oral delivery" as mentioned in the Office Action. Since Balschmidt et al. describes an injectable composition, this feature is thus another ground for distinguishing the invention from the cited reference.

For the reasons above, therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim1 and claims 6 and 39 which depend directly from claim 1, over Balschmidt et al. under §102(b).

In §10 of the Office Action, (composition) claims 1, 4, 5 and 37 are rejected under §102(b) over USP 5,120,712 to Habener. This rejection is respectfully traversed.

As pointed out in applicants' previous response, Habener teaches to administer the compositions described therein, "intravenously, intramuscularly or subcutaneously", and thus these materials are not "oral pharmaceutical comoposition[s]" as recited in applicants' claim 1. As is mentioned in the discussion above concerning the rejection of claims 1, 6 and 39 over the Balschmidt et al. reference, applicants have amended claim 1 to more clearly recite their invention such that, as now constituted, it recites (1) an oral pharmaceutical composition - not a pharmaceutical composition 'for oral delivery'; (2) that provides enhanced bioavailability of the orally delivered physiologically active peptide agent; (3) wherein such enhanced bioavailability is provided due to amidating the peptide active agent at a location where it is not naturally amidated. There is no recognition evidenced in the Habener reference applied in ¶10 of the

Office Action that amidating the peptide at the indicated location (i.e., where it is not naturally amidated) will have any effect on the bioavailability of the subject peptide.

Additionally, the presently claimed formulation is recited in claim 1 as being an "oral pharmaceutical composition", not a composition adapted "for oral delivery" as mentioned in the Office Action. Since Habener describes an injectable composition, this is thus another ground for distinguishing the invention from the cited reference.

For the reasons above, therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim1 and claims 4, 5 and 37 which depend directly or indirectly from claim 1, over the Habener reference under §102(b).

In ¶11 of the Office Action, (composition) claims 1, 4, 5, 40 and 41 are rejected as anticipated under §102(b) over the Barbier et al. U.S. Patent No. 6,110,892. This rejection is also respectfully traversed for essentially the same reasons as the rejection above based on the '712 patent to Habener. That is, Barbier et al. discloses, for example, amidated PTH 1-31 (PTH[1-31]-NH_2), but teaches to administer the formulation via injection. As noted above, applicants have amended claim 1 to more clearly recite their invention such that, as now constituted, it recites (1) an oral pharmaceutical composition - not a pharmaceutical composition 'for oral delivery' (or an injectable composition, for that matter); (2) that provides enhanced bioavailability of the orally delivered physiologically active peptide agent; (3) wherein such enhanced bioavailability is provided due to amidating the peptide active agent at a location where it is not naturally amidated. There is no recognition evidenced in Barbier et al. that amidating the peptide at the indicated location (i.e., where it is not naturally amidated) will have any effect on the bioavailability of the subject peptide. Additionally, per the discussion above, the presently claimed formulation is recited in claim 1 as being an "oral pharmaceutical composition", not a composition adapted "for oral delivery" as mentioned in the Office Action. Since Barbier et al. describes an injectable composition, this is thus another ground for distinguishing the invention from the cited reference.

For the reasons above, therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim1 and claims 4, 5, 40 and 41 which depend directly or indirectly from claim 1, over the Barbier et al. reference under §102(b).

Still further, in ¶12 of the Office Action claims 1, 4, 5, 40, 42, 45, 47, 58 and 60 are rejected as anticipated under §102(e) by the Peri et al. U.S. Patent Application Publication No. 2004/0023882. These rejections are respectfully traversed as well.

Peri et al. is directed to parathyroid hormone derivatives, including the 1-31 and 1-34 fragments deemed useful in the present invention. According to the reference, however, the focus is on the development of trans-dermal formulations which, as such, must be formulated in a manner that is substantially resistant to skin proteases. Applicants do not dispute that the subject reference discloses the PTH fragments used in the compositions and methods of the presently claimed invention. However, whereas the presently claimed formulation is "an oral pharmaceutical composition" and the method recited in claim 45 is directed to increasing the bioavailability of an "orally delivered" physiologically active peptide agent, the Peri et al. published application contains no teaching regarding the oral delivery of these materials. Peri et al. mentions, in passing, oral delivery of beta lactam derivatives of PTH(1-31) at, for example, paragraph 6 on p. 1 of the reference, but then the reference goes on to state [in ¶6] that, "The route of administration poses different challenges for formulating the . . . compound due to the differences in absorption, degradation, bioavailabilty, pharmokinetics, the metabolite composition of the circulating peptides, immunogenicity and other parameters." This can hardly be construed as a teaching of how to make an orally deliverable peptide formulation.

Further to the above, the Examiner directs applicants' attention to paragraph 64 of the Peri et al. reference as allegedly containing a teaching to oral delivery of the PTH fragments. Applicants submit, however, that a close reading of the indicated paragraph establishes that oral delivery is just one of a number of delivery modes included in a 'laundry list' of such modes provided in paragraph 64. There is no teaching contained in the subject paragraph regarding just how one is to effect such oral delivery, taking into account the factors (noted above) recited in paragraph 6 of the reference. Paragraph 64 additionally states that "techniques and formulations may generally be found in *Reminington's Pharmaceutical Sciences* (citation omitted). Applicants have reviewed the subject text, however, and found that while it does disclose certain oral drug dosage forms, e.g., tablets, it contains no disclosure whatever relating to oral delivery of a protein or a peptide, such as is the subject of the present invention. It is not appropriate, therefore, to base an 'obviousness' rejection under §103 upon a brief mention by Peri et al. of

"oral delivery" and a reference, i.e., Reminington, which contains no teaching relating to oral delivery of proteins and/or peptides. As indicated above, neither Peri et al. or Reminington, taken alone or in combination, would teach or even suggest to one having ordinary skills in this art what steps, modifications, etc. must be undertaken to deal with the concerns, i.e., absorption, degradation, bioavailability, etc. recited in paragraph 6 of the Peri et al. publication.

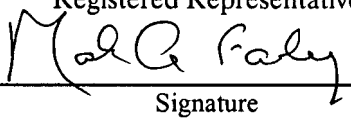
For all the reasons above, therefore, the Examiner is respectfully requested to reconsider and withdraw the §102(e) rejection based on Peri et al.

Summary

The claim amendments and remarks provided above and in applicants' prior response are believed to overcome all of the objections and rejections set forth in the present Office Action concerning this case. The Examiner is, therefore, respectfully requested to reconsider and withdraw the objections and rejections and to pass this application through to allowance. If the Examiner believes that an interview would advance the prosecution of this case, he is respectfully invited to telephone applicants' representative at the number below in order that such an interview may be arranged.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 7, 2007:

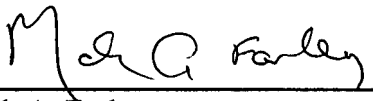
Mark A. Farley
Name of applicant, assignee or Registered Representative



Signature

May 7, 2007
Date of Signature

Respectfully submitted,



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